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Applicant argues that nothing in the references teaches or suggests adding a degradation FAOD to the sample as a pretreatment so that a glycated amino acid as a contaminant present in the sample is degraded and removed from the sample by the degradation FAOD and glycated protein as the analyte remains in the sample, as required by independent claim 1, and nothing in the references teaches or suggests using a pretreatment reagent containing a first FAOD that is present in an amount suitable for the degradation of a glycated amino acid as a contaminant present in the sample as required by claim 9.

However, According to specification (page 2 lines 30-33), a FAOD used for degrading the glycated amino acid is referred to as a “degradation FAOD”, and a FAOD used to measure the glycated protein is referred to as a “measurement FAOD”, and according to specification (page 4 lines 29-35), the measurement FAOD acts on both a glycated α-amino- group and a glycated side-chain amino group. Komori et al. teach causing a fructosyl amino acid oxidase (FAOD) to act on a glycated amino acid, the FAOD catalyzes a reaction represented by formula (1), and in formula (1) the α-amino-group is glycated, and in the formula (1) when an amino acid side chain group is glycated (p.4 003, 0034, and 0036). Therefore, the claimed “measurement FAOD” is met by Komori et al.

Komori et al. also teach FAOD treatment can be done separately or simultaneously, protease treatment + FAOD treatment (step 3), FAOD treatment + redox treatment (step 4), and the order of adding the FAOD is not limited (p.7 0061 step 3 and 0062). Therefore, Komori et al. teach pretreatment with a measurement FAOD, and adding a measurement FAOD during the redox reaction. Komori et al. further teach conditions of the FAOD treatment are determined as appropriate depending on the type of FAOD used, the type and the concentration of the glycated proteins (p.6 0054).

Moreover, according to the specification (p.4 lines 26-27), the “degradation FAOD” is specific for a glycated α-amino group. Yoshida et al. teach FAODs (derived from *Aspergillus terreus* and from *Fusarium oxysporum*), are active towards the model compounds of the glycated proteins in blood. Yoshida et al. teach the most commonly glycated site of albumin is the ε-amino group of the lysine residue (the amino group on the side chain of the lysine residues), and that of glycated hemoglobin (HbA1c) is the N-terminal valine (glycated α-amino group), therefore, Z-Lys(Fru) and Fru-Val are taken to be model compounds (p.499 2nd column 1st paragraph lines 1-4 & 7-12, and 1st column end paragraph). Yoshida et al. teach FAODs with different substrate specificities, applicable in the enzymatic measurement of the glycated albumin, and for enzymatic measurement of glycated hemoglobin (Introduction 2nd column 1st paragraph). Yoshida et al. further teach *Fusarium* (FAOD) enzyme showed high activity toward ε-glycated compounds and the *Aspergillus* enzyme acted on ε-glycated and α-glycated molecules to same degree, and the FAOD from *Penicillium janthinellum* showed higher activity toward Fru-Val, which is expected to be applicable to the enzymatic determination of glycated hemoglobin (Abstract, p.504 2nd column 1st paragraph lines 3-7, and 3rd paragraph lines 7-10). The FAOD(s) taught by Yoshida et al. are equivalent of FAOD(s) disclosed in the specification and perform the same function specified in the claims. Therefore, the claimed “degradation FAOD” is met by Yoshida et al.

Yoshida et al. further teach the enzymatic measurement of glycated proteins described in this report is not specific for glycated albumin among glycated proteins in blood, because lysine residues in proteins other than albumin may also be glycated, however, the amount of “total glycated serum protein” is known to be a more sensitive indicator of the great fluctuations in the blood glucose level generally associated with insulin-dependent diabetes (p.504 2nd column 3rd paragraph lines 1-7).

Therefore, a person of ordinary skill in the art at the time the invention was made could have been motivated to combine the prior art teachings and to modify the method as taught by Komori et al. by using a degradation FAOD in the pretreatment step and in the pretreatment reagent according to the teachings of Yoshida et al. to provide a method of measuring an amount of a glycated protein with predictable results of degrading/removing a glycated amino acid (contaminant) present in the sample by the FAOD enzyme. The motivation as taught by Yoshida et al. would be the interference caused by the glycation of amino groups in the side chain of the amino acid residue(s) of blood proteins (other than the glycated protein to be measured). Accordingly, once a method of measuring an amount of a glycated protein in an analyte was established, providing a measuring kit to determine the amount of the glycated protein would become obvious. The motivation would be to provide a measuring kit for the purpose of the diagnosis of diabetes. Applicant is directed to pages 12-13 of KSR v Teleflex (500 US ___ 2007) “ … the Court has held that a “patent for a combination which only unites old elements with no change in their respective functions . . . obviously withdraws what is already known into the field of its monopoly and diminishes the resources available to skillful men.” Great Atlantic & Pacific Tea Co. v. Supermarket Equipment Corp., 340 U. S. 147, 152 (1950). This is a principal reason for declining to allow patents for what is obvious. The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.”